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TITLE: In-Home Exposure Therapy for Veterans with PTSD

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14. ABSTRACT

We have set up a study that will provide a certain type of exposure therapy, called prolonged exposure therapy (PE) to military Veterans. We will ask 272 Veterans to participate in the study. Our goal is to compare PE conducted in three different ways: (1) PE that is office-based (OB; Veterans come to the clinic to meet with the therapist), (2) PE delivered via home-based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We will be checking to see if symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). We have now been referred 311 veterans. Of the 311 referred, including 263 males (85%) and 48 females (15%), 30 veterans (10% of those referred) have been randomized to the study. Of the 30 randomized participants, 19 (63%) are currently in Prolonged Exposure therapy, 5 (17%) have completed therapy and 6 (20%) have dropped out of therapy.

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INTRODUCTION:

This research study will provide a certain type of exposure therapy, called prolonged exposure therapy (PE) to military Veterans. We will ask 272 Veterans to participate in the study. Our goal is to compare PE conducted in three different ways: (1) PE that is office-based (OB; Veterans come to the clinic to meet with the therapist), (2) PE delivered via home-based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We will be checking to see if symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). However, the delivery of IHIP may cost more than the delivery of PE via the other modalities. We expect that the treatment, conducted in all three ways, will reduce the distress caused by PTSD symptoms in most of the participants, which will help to improve the lives of Veterans, their families, and society. The findings of this study will also benefit military Veterans and Active Duty military personnel by investigating new ways for treating PTSD so that the most effective treatments can be made widely available. We will also learn the best ways to manage urgent situations, such as a physical or emotional crisis, that occur when providing treatment in homes and through video technology.

BODY:

Our focus in the past year (30 Sept 2013 – 29 Sept 2014) has been to accomplish the tasks outlined in the Statement of Work (SOW) under Tasks 2. Namely, we continue to recruit from multiple clinic sites, meet with clinical staff and San Diego VA veterans to introduce the project, establish liaisons, and generate referrals. The study staff has been actively receiving referrals and scheduling interviews. We have arranged to have our study advertised on the TV screens around the VA hospital and community-based outpatient clinics, and that has generated many self-referrals to the project.

Assessment clinicians are actively administering informed consent and conducting comprehensive baseline assessments with potential participants as well as assessments at post-treatment and follow-up. We also have used the randomization scheme developed by the study statistician to randomize eligible participants to therapy.

Our treatment clinicians are providing the manual-guided evidence-based PTSD intervention. Therapists also attend a weekly PE Consultation Team meeting with Dr. Thorp. We also have weekly in person meetings with our local study personnel, a separate meeting for the assessment team, and another meeting for research assistants.

We continue to consult with members of the Home-Based Primary Care team in San Diego, including Co-Investigator Julie Wetherell, to determine best practices for delivering treatment within Veterans' homes. Our foremost concern is safety, and we will

have ongoing discussions about ways to maximize safety of Veterans and therapists in all three conditions.

We continue to use our developed recruitment materials, including brochures and flyers, and we use internal advertisements for the project (e.g., newsletters, messages on VA TVs and VA website). We have also determined the primary recruitment sites for the project.

The study database is complete and the project coordinator is overseeing data entry conducted by research assistant and study staff. We are using the study database to enter study data collected at different assessment and treatment time points.

We have completed all five of our pilot subjects. All pilot subjects completed treatment and post-treatment assessment, and they are now in the follow-up phase. These pilot sessions helped us refine our procedures for recruitment, telephone screening, consent, assessment, the VTC modality, and treatment. Of the 5 who were enrolled in the pilot study, 4 (80%) are male, and 1 (20%) is female. All five (100%) identified as Caucasian. We prepared and submitted a manuscript based on what we have learned from these pilot subjects, entitled *A pilot study of home-based psychotherapy for posttraumatic stress disorder* (see full reference below).

For the full project sample, we have been referred 311 veterans. Of the 311 referred, including 263 males (85%) and 48 females (15%), 30 veterans (10% of those referred) have been randomized to the study. Of the 30 randomized participants, 19 (63%) are currently in Prolonged Exposure therapy, 5 (17%) have completed therapy and 6 (20%) have dropped out of therapy.

The 6 who dropped out included three (50%) who stopped attending their therapy sessions for unknown reasons and did not respond to phone calls and letters from study personnel, two (33%) who reported not feeling able to continue with the imaginal exposure component of treatment, and one (17%) who cited personal problems interfering with participation.

Of the 311 referred, 276 (89% of the total referred) have not been enrolled. Of those who were not enrolled, 17 Veterans (3% of the totals referred) are pending: contact is in progress with 7 (2%), 7 (2%) have requested to be contacted at a later date to be screened and 3 (1%) have yet been contacted. Of the 23 Veterans who have not been screened, 23 (5%) were unreachable.

One-hundred and twenty veterans were (39%) were screened by telephone and deemed ineligible for the in-person baseline assessment. After conducting the phone screen and being deemed eligible for the baseline assessment, 3 Veterans (1%) are to be contacted for baseline scheduling, 15 (5%) are on a hold (either waiting for their current PTSD treatment to end, waiting to be on a stable dosage of medications for two months, or waiting for personal reasons such as vacation or surgery) and 92 (30%) Veterans were not interested in participating in the baseline assessment.

Forty-one veterans were scheduled for upcoming baseline assessments to determine eligibility, five (2%) were assigned as pilot subjects, and thirty (10%) were randomized

to the full study. Five Veterans (2%) were deemed ineligible for the study after the baseline assessment and one no-showed to the study scheduled baseline appointment.

Of the 30 who were randomized, 25 (83%) are male and 5 (17%) are female. The racial/ethnic information for the 195 randomized veterans is as follows: 11 (37%) identify as African American, 10 (33%) identify as Caucasian, 6 (20%) identify as Hispanic/Latino, 2 (7%) identify as Asian, and 1 (3%) identify as American Indian/Alaskan Native.

KEY RESEARCH ACCOMPLISHMENTS:

- We have obtained VA San Diego IRB and R&D Approval to conduct our study (IRB #H130390). HRPO has provided initial approval (and most recent re-approval on August 13, 2014).
- We have hired all personnel, and have completed training with all personnel.
- We continue to consult with national experts about in-home provision of care (through teleconferencing and in-person).
- We have purchased equipment and supplies for the project and prepared paperwork (including recruitment materials).
- We created an Access Database for study data entry.

REPORTABLE OUTCOMES:

- manuscripts, abstracts, presentations;
    - Dr. Leslie Morland presented progress of our study at the Military Operational Medicine Research Program (MOMRP) Joint Program Committee for Military Operational Medicine (JPC5) In Progress Review (IPR) meeting on 4 August 2014
    - Manuscript submitted to Psych Services for publication: Thorp, S. R., Soto Morales, J., Wells, S. Y., Moreno, L., Walter, K. H., Howard, I. C., Morland, L. A. (2014). *A pilot study of home-based psychotherapy for posttraumatic stress disorder*. Manuscript submitted for publication.
- patents and licenses applied for and/or issued;
    - None
- degrees obtained that are supported by this award;
    - None
- development of cell lines, tissue, or serum repositories;
    - N/A
- informatics such as databases and animal models, etc.;
    - An Access Database has been created for use of the present study data entry.
- funding applied for based on work supported by this award;
    - None
- employment or research opportunities applied for and/or received based on experience/training supported by this award.
    - None

CONCLUSION:
We have enrolled 10% of the projected sample size and are making good progress toward recruitment goals. We continue to receive referrals for the study and continue to make screening and randomizing a priority to moving forward with the study. However, due to the amount of referrals and limited amount of therapy slots, we are not equipped with the necessary availability of therapy times to enroll participants. In the past year, we learned that a 10 mile radius for veterans within the San Diego city center was not helpful for recruitment as it was very difficult to enroll participants; therefore we increased the zip code radius to 15 miles. The larger radius has greatly increased study enrollment by including those participants that were previously excluded solely due to radius. With the larger radius, study therapists drive time is increased and hence only able to see 2 participants a day for the In-Home, In-Person treatment arm. We have determined that an increase in therapist availability will allow us to increase the amount of participants we see in this study. This increase in therapy times for patients to be seen for treatment will allow our study to enroll and randomize 272 participants, as stated under Task 2, Statement of Work.

We have made good progress on the project. We obtained regulatory approvals, hired and trained all personnel, consulted with experts as needed, purchased equipment and supplies, prepared paperwork and recruitment materials, and prepared our database. We have submitted a manuscript for publication on lessons learned from our pilot sample.

REFERENCES:
None

APPENDICES:
None

SUPPORTING DATA:
None